

**WHAT IS CLAIMED IS:**

1. A controller for controlling the temperature and flow of a heat exchange fluid within a circuit, the circuit comprising a heat exchange catheter insertable within a patient, an external heat exchanger, and a pump for flowing heat exchange fluid through the circuit,  
5 the controller comprising:

a heat and/or cold generating element, the generating element being in thermal contact with the external heat exchanger containing the heat exchange fluid;

10 a patient sensor positioned and configured to generate a signal representing a biophysical condition of a patient;

a microprocessor connected to receive the signal from the patient sensor and being responsive to the signal to control the generating element;

a mechanical drive unit for activating the pump contained in the circuit; and

15 a safety sensor for detecting a fluid parameter in the circuit and generating a safety signal representative of the presence or absence of the fluid parameter, the safety signal being transmitted to the microprocessor that responds by controlling the operation of the pump.

2. The controller of claim 1 wherein the sensor is a bubble detector and the fluid  
20 parameter is gas entrained in the heat exchange fluid, and wherein the safety signal represents the presence of bubbles within the circuit.

3. The controller of claim 1, wherein the sensor comprises an optical fluid level detector positioned to optically sense the fluid level within the circuit.  
25

4. The controller of claim 3, wherein the optical fluid level detector includes an optical beam source and an optical sensor, wherein the optical beam source and optical sensor are positioned adjacent the circuit to sense the level of fluid therein.

30 5. The controller of claim 1 further comprising a plurality of the patient sensors for sensing biophysical conditions of a patient, the microprocessor being responsive to

each of the sensors to control the generating element.

6. The controller of claim 5, wherein the microprocessor is configured to compare the signals from at least two of the plurality of patient sensors and produce an  
5 alarm condition when the signals do not agree.

7. The controller of claim 1 wherein the microprocessor further receives a target temperature input, and the signal represents a sensed patient temperature, the microprocessor is configured to add heat to the fluid if the target temperature is above the  
10 patient temperature and remove heat from the fluid if the target temperature is below the patient temperature, and wherein the microprocessor responds to the signal from the patient sensor with a proportional integrated differential (PID) response such that the rate at which patient temperature approaches the target temperature is controlled.

15 8. A heat transfer catheter flow system, comprising:  
a heat transfer medium circulation loop including a heat transfer catheter insertable within a patient, a heat transfer unit, and conduits coupled to the heat transfer catheter and heat transfer unit that enable circulation of a heat transfer medium therebetween;  
20 a pump head in contact with heat transfer medium within the circulation loop for circulating heat transfer medium through the circulation loop;  
a cassette including the heat transfer unit and containing the pump head;  
a controller with which the cassette mates, the controller including a pump motor, wherein the pump head engages the pump motor when the cassette is mated  
25 with the controller;  
a microprocessor connected to control the speed of the pump motor; and  
an electronic feedback loop including the microprocessor that detects a back torque experienced by the pump motor and responsively controls the speed of the pump motor.

30 9. The system of claim 8, wherein the controller includes a cavity for receiving

the cassette, and wherein the heat transfer unit includes an external heat exchanger including an outer flexible layer at least partly defining a flow channel therein, the flexible layer expanding outward upon flow of heat exchange medium through the flow channel, wherein the controller includes a heat and/or cold generating element facing the cavity that

5 exchanges heat with the heat exchange medium in the flow channel through the flexible layer, the cavity being sized such that outward expansion of the flexible layer causes the external heat exchanger to be compressively retained within the cavity.

10. The system of claim 8, wherein the controller includes a cavity for receiving  
10 the cassette, the pump motor being positioned adjacent the opening of the cavity.

11. A controller for controlling the temperature and flow of a heat exchange fluid within a circuit, the circuit comprising a heat exchange catheter insertable within a patient, an external heat exchanger, and a pump for flowing heat exchange fluid through the circuit,  
15 the controller comprising:

a heat and/or cold generating element, the generating element being in thermal contact with the external heat exchanger containing the heat exchange fluid;

20 a mechanical drive unit for activating the pump contained in the circuit for pumping the heat exchange fluid;

a microprocessor connected to control both the generating element and the mechanical drive unit; and

25 a safety system for detecting problems in the circuit, the safety system including a plurality of sensors that generate signals indicative of respective parameters of the system and/or patient, the signals being transmitted to the microprocessor that responds by controlling the operation of the generating element and the mechanical drive unit.

12. The controller of claim 11, wherein the safety system includes a sensor for  
30 detecting the fluid level within the circuit.

13. The controller of claim 11, wherein the safety system includes a sensor for detecting the temperature of a location within the patient.

14. The controller of claim 13, further including a redundant sensor for detecting  
5 the temperature of a location within the patient, the microprocessor being responsive to a difference in the temperatures sensed by the sensor and the redundant sensor.

15. The controller of claim 11, wherein the safety system includes a sensor for detecting bubbles within the circuit.

10

16. The controller of claim 11, wherein the safety system includes a sensor for detecting the operating status of the generating element.

15

17. The controller of claim 20, wherein the safety system includes a sensor for detecting the operating status of the mechanical drive unit.

20

18. A heat transfer catheter system comprising:  
a heat transfer catheter;  
a heat transfer unit defining a flow channel between opposite sidewalls, one of the sidewalls being relatively thin and flexible and providing minimal thermal insulation, while the opposite sidewall being relatively non-flexible so as to provide structural support to the heat transfer unit; and  
conduits coupled to the heat transfer catheter and heat transfer unit that enable circulation of a heat transfer medium therebetween.

25

19. The system of claim 18, further including a controller having a cavity for receiving the heat transfer unit, the controller having a heat and/or cold generating element therein positioned adjacent the flexible sidewall when the heat transfer unit is inserted within the cavity.

30

20. The system of claim 19, wherein the flexible sidewall expands outward upon

flow of heat exchange medium through the flow channel, and wherein the cavity is sized such that outward expansion of the flexible sidewall causes the heat transfer unit to be compressively retained within the cavity.

5        21. The system of claim 18, wherein the flexible sidewall attaches to the opposite sidewall around their respective edges, and along a series of lines within the edges such that the flow channel defines a serpentine path therethrough.

10      22. The system of claim 18, wherein the heat transfer unit further includes a relatively rigid bulkhead including a fluid reservoir and a pump head, the combination of the heat transfer catheter, conduits, flow channel, fluid reservoir, and pump head defining a flow circuit through the system.

15      23. A method of regulating the temperature of a patient, comprising:  
          providing a heat exchange catheter system including a heat exchange catheter having a fluid path therethrough, a pair of conduits fluidly connected to the heat exchange catheter, and an external heat exchanger connected via the conduits to circulate heat exchange medium through the exchange catheter;  
          providing a first controller adapted to couple to the external heat exchanger of the heat exchange catheter system, the first controller including a heat and/or cold generating element therein for exchanging heat at a first rate with the heat exchange medium within the external heat exchanger;  
          providing a second controller adapted to couple to the external heat exchanger of the heat exchange catheter system, the second controller including a heat and/or cold generating element therein for exchanging heat at a second rate with the heat exchange medium within the external heat exchanger;  
          coupling the heat exchange catheter system with the first controller;  
          inserting the heat exchange catheter into the patient;  
          regulating the temperature of the patient by exchanging heat at the first rate between the generating element of the first controller and the external heat exchanger;

de-coupling the heat exchange catheter system from the first controller;  
coupling the heat exchange catheter system with the second controller; and  
regulating the temperature of the patient by exchanging heat at the second  
rate between the generating element of the second controller and the external heat  
exchanger.

5           24. The method of claim 23, wherein the first controller and the second controller  
are the same physical device.

10          25. The method of claim 23, wherein the first rate of heat exchange is  
substantially greater than the second rate of heat exchange.

15          26. The method of claim 25, wherein the first controller is substantially larger than  
the second controller.

15          27. The method of claim 26, wherein the first controller includes a housing on  
wheels and is supplied with power through an outlet.

20          28. The method of claim 26, wherein the second controller includes an internal  
battery.

25          29. The method of claim 26, wherein the second controller is configured to  
attach to a hospital bed.

25          30. A method of controlling the rate of change of a patient's body temperature  
using a heat transfer catheter and associated controller, comprising:

               providing a heat transfer catheter for insertion into a body cavity, the heat  
transfer catheter having a heat transfer region thereon;

30           sensing the patient's body temperature in the body cavity or in another  
location;

               determining the temperature of the catheter heat transfer region;

providing a controller in communication with the heat transfer catheter via conduits, the controller being adapted to elevate or depress the temperature of the catheter heat transfer region relative to the body temperature;

selecting a target temperature different than the body temperature;

5 selecting a ramp rate equal to the time rate of change of temperature from the body temperature to the target temperature;

setting the temperature of the catheter heat transfer region based on the ramp rate;

10 monitoring the temperature differential between the target temperature and the body temperature; and

reducing the ramp rate when the temperature differential reduces below a predetermined threshold.

31. The method of claim 30, wherein the heat transfer catheter and conduits  
15 define a fluid circulation path therethrough, and wherein the step of setting the temperature of the catheter heat transfer region comprises setting the temperature of a circulating fluid within the fluid circulation path.

32. The method of claim 31, wherein the step of determining the temperature of  
20 the catheter heat transfer region comprises sensing the temperature of the circulating fluid.

33. The method of claim 32, further including comparing the target temperature and the temperature of the circulating fluid and using the comparison to adjust the temperature of the circulating fluid

25

34. The method of claim 30, wherein the controller includes a microprocessor, and wherein the steps of monitoring and reducing are accomplished automatically by the microprocessor.

30 35. The method of claim 30, wherein steps of sensing, determining, and monitoring are accomplished at rates of multiple times a second.

36. The method of claim 30, further including:  
providing operator inputs for the controller to enable manual adjustment of the target temperature and the ramp rate.

5